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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,122	05/10/2001	Randall S. Alberty	PHA-007.01	7413
25181	7590	03/24/2004	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP, WORLD TRADE CENTER WEST 155 SEAPORT BLVD BOSTON, MA 02110			COLLINS, CYNTHIA E	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 03/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,122

Applicant(s)

ALBERTE ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-15 and 21-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-15 and 21-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1203.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

The Amendment filed December 19, 2003 has been entered.

Claims 1-12 and 16-20 are cancelled.

Claims 13-15 are currently amended.

Claims 21-60 are newly added.

Claims 13-15 and 21-60 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449 filed December 19, 2003 is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 21-22, 25-26, 29-31, 33-35, 37-45 and 49-57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 21-22 and 25-26 are drawn to amino acid and nucleotide sequences having at least 90% or 99% identity with SEQ ID NOS:16 or 15. The limitations requiring at least "90%" or "99%" identity do not find support in the specification as filed and thus constitute new matter.

Claims 13-15 remain rejected, and claims 21-22, 25-26, 29-31, 33-35, 37-45 and 49-57 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed June 17, 2003.

Applicants' arguments filed December 19, 2003 have been fully considered but they are not persuasive.

Applicants argue that the rejection should be withdrawn in view of the cancellation of claims 1-7, 9, 11 and 20 and the amendment of claims 14 and 15. Applicant additionally asserts that the specification provides an adequate description of the amended and newly submitted claims because the specification teaches the nucleotide and amino acid sequences of a *Zostera marina* sulfotransferase, SEQ ID NOS:15 and 16 respectively (reply page 12).

The rejection is maintained as the pending claims are not limited to the nucleotide and amino acid sequences of SEQ ID NOS:15 and 16. The pending claims are currently drawn to isolated nucleic acid sequences that include sequences comprising SEQ ID NO:15, subsequences of at least 50 nucleotides of SEQ ID NO:15, sequences that hybridize to SEQ ID NO:15, sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16, and

sequences having at least 90% or 99% identity with SEQ ID NO:15. However, the specification does not describe which 50 base pair fragments of the 1192 base pairs of SEQ ID NO:15 retain the sulfotransferase activity of the encoded polypeptide. The specification also does not describe the structural features of SEQ ID NO:15 that are retained by sequences that hybridize to SEQ ID NO:15 and that encode a polypeptide having sulfotransferase activity. The specification additionally does not describe the structural features of SEQ ID NO:15 that are retained by sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16 and having sulfotransferase activity. The specification further does not describe the structural features of SEQ ID NO:15 that are retained by sequences having at least 90% or 99% identity with SEQ ID NO:15 and that encode polypeptides having sulfotransferase activity. The structural features unique to the claimed genus of sequences are not described, and the single nucleotide sequence disclosed in the specification (SEQ ID NO:15) encoding a single amino acid sequence (SEQ ID NO:16) having a moderate level of homology to known flavonol sulfotransferases does not constitute a representative number of species adequate to support the description of the multiple sequence variants of SEQ ID NOS:15 and 16 encompassed by the claimed genus of sequences.

Claims 13-15, 21-22, 25-26, 29-31, 33-35, 37-45 and 49-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid of SEQ ID NO:15 and an isolated nucleic acid encoding SEQ ID NO:16, as well as vectors, cells and plants comprising said isolated nucleic acids, does not reasonably provide enablement for other nucleotide or amino acid sequences, or for vectors, cells and plants

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comprising other nucleotide or amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants' arguments filed December 19, 2003 in response to the prior rejection of claims 1-9, 11, 13-15 and 20 as failing to comply with the enablement requirement have been fully considered but they are not fully persuasive.

At page 13 of their reply, Applicants point to the exemplification at page 77 of the specification in support of SEQ ID NO:16 exhibiting a sulfotransferase activity. Applicants additionally assert that sulfotransferase is the only protein whose presence is necessary in plants for converting coumaric acid into zosteric acid, that the antifouling properties of zosteric acid are well known, that essentially all plants are known to exhibit levels of coumaric acid sufficient to provide a substrate for an expressed sulfotransferase, and that sulfotransferases are not subject to positive or negative regulation (reply pages 13-14).

In view of Applicants' response, and in view of the current claim amendments and newly added claims, the rejection of the claimed invention for non-enablement is withdrawn. However, claims 13-15, 21-22, 25-26, 29-31, 33-35, 37-45 and 49-57 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable the full scope of the invention as currently claimed.

Claims 13-15, 21-22, 25-26, 29-31, 33-35, 37-45 and 49-57 are now drawn to isolated nucleic acid sequences that include sequences comprising SEQ ID NO:15, subsequences of at least 50 nucleotides of SEQ ID NO:15, sequences that hybridize to SEQ ID NO:15, sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16, and sequences

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having at least 90% or 99% identity with SEQ ID NO:15. However, the specification discloses only one nucleotide sequence (SEQ ID NO:15) encoding only one amino acid sequence (SEQ ID NO:16) that exhibits sulfotransferase activity. The specification does not disclose subsequences of at least 50 nucleotides of SEQ ID NO:15, sequences that hybridize to SEQ ID NO:15, sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16, and sequences having at least 90% or 99% identity with SEQ ID NO:15 that encode polypeptides having sulfotransferase activity.

Guidance for making and using these other sequences is necessary for enablement because it is unpredictable whether they would encode polypeptides having sulfotransferase activity, since a change in as few as one nucleotide in a base sequence, such as would occur in subsequences of at least 50 nucleotides of SEQ ID NO:15, sequences that hybridize to SEQ ID NO:15, sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16, or sequences having at least 90% or 99% identity with SEQ ID NO:15, can alter the amino acid sequence of an encoded polypeptide, and a change in as few as one amino acid in a polypeptide can alter or eliminate its function. See, for example, Rhoads et al. (J. Biol. Chem., November 1998, Vol. 273, No. 46, pages 30750-30756), who teach that mutation of Cys-128 to Ala in an *Arabidopsis* alternative oxidase caused a pronounced overall increase in enzyme activity relative to the wild-type in the presence or absence of pyruvate (page 30753 Figure 3). Mutation of Cys-78 to Ala in the same *Arabidopsis* alternative oxidase resulted in a minimally active enzyme that showed no response to added pyruvate (page 30753 Figure 3).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, it would require undue experimentation for one skilled in the art to determine which of the claimed

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nucleotide or amino acid sequences would encode polypeptides having sulfotransferase activity and which would not.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Remarks

Claims 13-15 and 21-60 are rejected.

Claims 23-24, 27-28, 32, 36, 46-48 and 58-60 would be allowed if rewritten so as not to depend from rejected claims.

Claims 13-15 and 21-60 are deemed free of the prior art due to the failure of the prior art to teach or suggest isolated nucleic acid sequences that include sequences comprising SEQ ID NO:15, subsequences of at least 50 nucleotides of SEQ ID NO:15, sequences that hybridize to

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SEQ ID NO:15, sequences encoding polypeptides having at least 90% or 99% identity with SEQ ID NO:16, and sequences having at least 90% or 99% identity with SEQ ID NO:15.

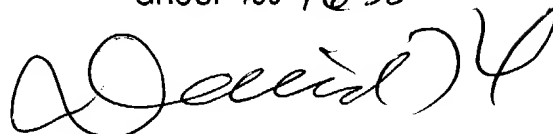
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CC

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a stylized flourish at the end.